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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,761	07/21/2003	John H. Laragh	55990/8	4847

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EXAMINER
SHEN, BIN

ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
10/16/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

klpatent@kramerlevin.com

Office Action Summary	Application No.	Applicant(s)	
	10/623,761	LARAGH, JOHN H.	
	Examiner	Art Unit	
	BIN SHEN	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner of your application in the USPTO was changed before the prior Office action. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Bin Shen.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 Aug 2008 has been entered.

The drawings received 8/22/2008 have been entered.

Status of the Claims

Claims 1-21 are cancelled. Claims 22-25 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The claims are drawn to a method of treating a hypertensive subject having a normal to above normal plasma rennin activity level. The claims in question recite a "said method does not include a washout period before step A" (in claims 22 and 23).

Lack of *Ipsis verbis* support

The specification is void of any literal support for the above listed phrases and numbers (and/or ranges). The words "washout" "wash" listed above were searched, and they were not found anywhere in the specification.

Lack of Implicit or Inherent Support

"While there is not in *haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure." See MPEP 2163. Thus support can be furnished implicitly or inherently for a specifically claimed limitation. However, the specification lacks any implicit or inherent support for the above listed claim limitations. As explained *supra*, there is no support for any concepts listed above. For example, no description/definition as to what "washout step" is, no explanation/implication that elimination of thus "washout" step is patentably distinct.

Rejection under 35 USC §103 is maintained despite the above New Matter rejection of the newly added limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over McMahon (1978). McMahon teaches that some clinics routinely test patients for plasma renin activity, and that these patients fall into three categories: low, medium, and high renin activity hypertensive patients. McMahon teaches that low renin patients can be administered a diuretic alone, i.e., a plasma volume-changing drug. Patients with higher plasma renin activity can be administered renin-blocking or -reducing drugs (see p. 3, for example). McMahon also teaches that it is standard practice, when one drug does not appear to be working, to add a second drug of a different type, i.e. if a diuretic is not working, add a renin-blocking agent, for example (see p. 4, for example). Lastly, McMahon teaches that one should treat the hypertension, not the renin level: because hypertension is a disease of high blood pressure, one must inherently monitor the blood pressure. McMahon also teaches that it is standard practice in treating hypertensive patients to titrate the drug to a proper dosage to eliminate the hypertension; determining proper dosage inherently involves measuring the blood pressure response to a given dosage.

A person of ordinary skill in the art at the time the invention was made would have been motivated to prescribe an anti-renin drug to a patient with medium to high PRA because McMahon teaches that such patients can be administered such drugs, and alternatively patients with low PRA should be administered diuretic drugs; additionally, McMahon teaches that it is standard practice to titrate dosage to achieve optimal amelioration of hypertensive symptoms, and because that doctors should treat the hypertension, it is inherent that blood pressure should be monitored because hypertension is a disease of high blood pressure.

Hence, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to prescribe a diuretic or renin-blocking drug based on PRA measurement, and to modulate dosages based on blood pressure response to drug administration.

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over McMahon (1978) in view of Laragh (1998).

The teachings of McMahon are discussed above and applied as before.

McMahon does not expressly teach that a threshold level of plasma renin activity is 0.65 ng/ml/h.

Laragh teaches exactly that threshold as a guide for diagnosing primary aldosteronism (see p. 171S, col. 2, for example). Laragh teaches that finding a baseline plasma renin activity for every new patient greatly facilitates drug choice. The goal is to find the primary pressor mechanism: high renin indicates an anti-renin drug, while low renin indicates an antivolume drug. Laragh further teaches that the PRA test guides, simplifies, and hastens the selection of the right single drug for each patient (see p. 171 S, col. 2, for example).

A person of ordinary skill in the art at the time the invention was made would have been motivated to treat a hypertensive with an anti-renin drug if their PRA was greater than 0.65 ng/ml/h because Laragh teaches that below that level the underlying pathology probably involves primary aldosteronism rather than renin-mediated hypertension.

Hence, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to prescribe a renin-blocking drug above 0.65 ng/ml/h PRA.

Applicant's arguments filed 8/22/2008 have been fully considered but they are not persuasive.

Applicants argue that McMahon does not disclose, teach or suggest the presently claimed invention and McMahon teaches away from the presently claimed invention since McMahon stresses importance of long washout period.

It is the examiner's position that newly added limitation "said method does not include a washout period before step A" constitutes new matter since the specification does not contemplate such negative limitation and does not provide a definition or guidance as to the meaning of this term. McMahon suggests it is possible to categorize a given patient as having "low-, normal- or high-renin hypertension" (page 4, lines 4-5), and McMahon teaches an initial measurement of a subject's PRA two weeks after taken them off from all antihypertensive drugs (page 3, lines 10-12). McMahon also teaches high renin patients respond well to renin-blocking or reducing drugs (page 3, lines 29-31). Therefore it would be obvious to one of ordinary skill in the art at the time the invention was made to measure initial PRA of a patient and treat normal to high PRA patient by administering different dosage of medications because it is common practice to measure blood pressure to monitor the efficacy of the hypertensive treatment (page 4).

Applicants argue that Laragh does not disclose or suggest a course of treatment based on an initial PRA measurement without use of a washout period.

It is the examiner's position that McMahon suggests/states that "there is a faction among clinicians that advocates the initial measurement of renin" and "use of renin as a guide to medication", and Laragh teaches that finding a baseline plasma renin activity for every new patient greatly facilitates drug choice, and that high renin indicates an anti-renin drug, while low renin indicates an antivolume drug, thus the PRA test guides, simplifies, and hastens the selection of the right single drug for each patient (see p. 171 S, col. 2, for example), and the specification does not contemplate the negative limitation of not include a washout step.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571) 272-0925.

B Shen

Art Unit 1657

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657